

### **REMARKS**

Claims 23-64 were pending. Claims 27-29 and 31-64 are cancelled without prejudice to Applicant's right to pursue their subject matter in the present application and in related applications. Claims 23, 24, 26 and 30 are amended without any intent of disclaiming equivalents thereof. New claims 65-75 are added. Accordingly, upon entry of this paper, claims 23-26, 30 and 65-75 will be pending and presented for consideration.

#### **Claim Amendments**

Claim 23 is amended to clarify that the present invention provides a kit suitable for rolling circle amplification. Claim 23 is also amended to replace "a plurality of single-stranded polynucleotide primers" with "at least one primer" and to further define the nature of the primer and the polymerase. Support for the amendments can be found throughout the specification at least, for example, on page 9, lines 14-18, page 38, lines 4-8, page 40, lines 1-7, the Examples section and Figures 8A and 8B.

Claims 24, 26 and 30 are amended to correct informalities and for clarification and consistency.

Support for new independent claim 69 can be found in the specification at least, for example, on page 9, lines 14-18, page 38, lines 4-8, page 40, lines 1-20, the Examples section and Figures 8A and 8B.

Support for new claims 65, 66, 74 and 75 can be found in the specification at least, for example, on page 18, lines 12-18.

Support for new claims 67 and 68 can be found in the specification at least, for example, on page 8, lines 16-18.

Support for new claims 70 can be found in the specification at least, for example, on page 10, lines 20-22, and on page 11, lines 19-21.

Support for new claims 70 can be found in the specification at least, for example, on page 10, lines 20-22, and on page 11, lines 19-21.

Support for new claims 71 can be found in the specification at least, for example, on page 12, lines 6-7.

Support for new claims 72 can be found in the specification at least, for example, on page 18, lines 4-6.

Support for new claims 73 can be found in the specification at least, for example, on page 40, lines 18-19.

Applicant submits that the amendments to the claims introduce no new matter.

*Specification Amendments*

Applicant have amended the title, the abstract, and updated the continuation information as suggested by the Examiner. Applicant submits that the amendments to the specification introduce no new matter.

*Claim Objections*

The Office Action objects to claims 31, 32, 41, 42, 52, 53, 63 and 64 under 37 C.F.R. §1.75(c) for allegedly failing to further limit the subject matter of the claims from which they depend.

Without acquiescing to the rejection and solely to advance prosecution, Applicant has cancelled claims 31, 32, 41, 42, 52, 53, 63 and 64 without prejudice, thus rendering the objections moot.

*Claim Rejection Under 35 U.S.C. §112, 2<sup>nd</sup> paragraph*

Claims 24, 27, 34, 37 and 43-64 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 27, 34, 37 and 43-64 have been cancelled without prejudice and without acquiescing to the rejections; therefore, all rejections with respect to these claims are moot.

With respect to claim 24, Applicant has amended claim 24 to replace the word “comprising” with “comprises” to address the Examiner’s concern. Accordingly, Applicant respectfully requests the rejection be withdrawn.

*Claim Rejection Under 35 U.S.C. §112, First Paragraph: Written Description*

Claims 23-64 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Without acquiescing to the rejection and solely to advance prosecution, Applicant has cancelled claims 27-29 and 31-64 without prejudice. Thus, the rejections with respect to claims 27-29 and 31-64 are moot.

With respect to remaining claims 23-26 and 30, the Office Action alleges that there was no support in the specification for the language “a plurality of single-stranded polynucleotide primers” recited in independent claim 23. The Office Action requests that specific support such as page and line numbers be provided.

Without acquiescing to the merits of the rejection, Applicant has amended independent claim 23 to replace the language “a plurality of single-stranded polynucleotide primers” with “at least one primer.” Support for the language “at least one primer” can be found in the specification at least, for example, in Figure 8A and 8B and in accompanying text, for example, on page 9, lines 15-16. Therefore, Applicant respectfully submits that claim 23 and its dependent claims 24-26 and 30 fully comply with the written description requirement. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

*Claim Rejection Under 35 U.S.C. §102*

Claims 23, 24, 33 and 34 stand rejected under 35 U.S.C. §102(b) as being anticipated by Mullis (U.S. Patent No. 4,683,195). Without acquiescing to the rejection and solely to advance prosecution, Applicant has cancelled claims 33 and 34 without prejudice. Thus, the rejection with respect to claims 33 and 34 is moot. Applicant traverses the rejection to the extent it is maintained over claims 23 and 24 as amended.

For a rejection to be proper under 35 U.S.C. §102, each and every element of the claimed invention must be identically disclosed or described in a single prior art reference. *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d (BNA) 1566, 1567 (Fed. Cir. 1990) (quoting *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q.2d (BNA) 1315, 1317 (Fed. Cir. 1988)). Emphasis added.

Independent claim 23, as amended, recites a kit suitable for rolling circle amplification comprising, *inter alia*, at least one primer comprising a sequence complementary to a site on a circular nucleic acid molecule such that the extension of the at least one primer forms a rolling circle replicon. Applicant submits that Mullis does not teach or suggest such a primer. Mullis teaches kits suitable for standard PCR amplification using two primers that hybridize to both ends of a target linear nucleic acid sequence. *See, e.g.*, Mullis, abstract, and column 8, lines 10-23. Mullis does not teach or suggest any primer having a sequence complementary to a site on a circular nucleic acid molecule as required by claim 23. Mullis also does not teach or suggest extension of the primer forming a rolling circle replicon. In fact, Mullis does not teach or suggest rolling circle amplification or any kit suitable for rolling circle amplification whatsoever. Therefore, Applicant submits that Mullis fails to anticipate claim 23 and its dependent claim 24 because Mullis does not teach or suggest at least one required element. Therefore, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

Claim Rejection Under 35 U.S.C. §103(a) Over Walker In View Of Mullis

Claims 23-64 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Walker (U.S. Patent No. 5,270,184) in view of Mullis. Without acquiescing to the rejection and solely to advance prosecution, Applicant has cancelled claims 31-64 without prejudice. Thus, the rejection with respect to claims 31-64 is moot. Applicant traverses the rejection to the extent it is maintained over remaining claims 23-26 and 30 as amended.

Even if the disclosures of Walker and Mullis were properly combined, which Applicant respectfully submits they are not, such a combination would not teach Applicant's invention as claimed in independent claim 23. As discussed above, independent claim 23, as amended, recites a kit suitable for rolling circle amplification comprising, *inter alia*, at least one primer

comprising a sequence complementary to a site on a circular nucleic acid molecule such that the extension of the at least one primer forms a rolling circle replicon. Walker teaches a method for generating nucleic acid sequences by strand displacement amplification technique employing two primers, one located 5' to the other on a linear nucleic acid sequence. *See, e.g.*, Walker, abstract, the Summary of the Invention, and Figures 1-4. Walker does not teach or suggest any primer having a sequence complementary to a site on a circular nucleic acid molecule as required by claim 23. Walker also does not teach or suggest extension of the primer forming a rolling circle replicon. Moreover, Walker does not teach or suggest any rolling circle amplification or any kits suitable for rolling circle amplification whatsoever.

Mullis does not correct the deficiency of Walker. As discussed above, Mullis does not teach or suggest any primer having a sequence complementary to a site on a circular nucleic acid molecule such that the extension of the primer forms a rolling circle replicon as required by claim 23. Therefore, the combination of Walker and Mullis, even if proper, does not provide the required at least one primer having a sequence complementary to a site on a circular nucleic acid molecule such that the extension of the primer forms a rolling circle replicon as claimed by Applicant. Accordingly, Applicant respectfully submits that claim 23 and any claims dependent therefrom are novel and unobvious over Walker in view of Mullis. Therefore, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 23 and dependent claims 24-26 and 30 under 35 U.S.C §103(a).

*Claim Rejection Under 35 U.S.C. §103(a) Over Lizardi*

Claims 23-64 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Lizardi (U.S. Patent No. 6,124,120). Applicant respectfully traverses the rejection because Lizardi is not a prior art reference. Lizardi was filed on October 8, 1997 and does not claim benefit to any prior application. The present application claims August 4, 1992 as its earliest priority date. Applicant submits that the subject matter claimed in the pending claims is at least entitled to a priority date of August 24, 1992, because the claimed subject matter is fully disclosed and enabled in the parent application U.S. Serial No. 07/933,945, filed on August 24, 1992. *See, e.g.*, U.S.S.N. 07/933,945, page 11, line 29 to page 12, line 2; page 43, line 22 to page 45, line 7; Figures 8A and 8B. Therefore, Applicant respectfully submits that Lizardi is not

a prior art reference and can not render obvious the pending claims in the present application. Accordingly, Applicant respectfully requests the rejection be withdrawn.

Double Patenting

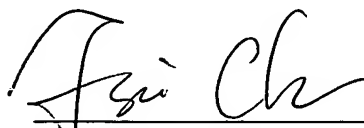
Claims 23-64 stand rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-29 of U.S. 6,740,745. Claims 23-64 also stand rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-20 of U.S. 6,448,017.

Applicant has cancelled claims 27-29 and 31-64 without prejudice and without acquiescing to the rejection. The rejections with respect to claims 27-29 and 31-64 are therefore moot. With respect to remaining claims 23-26 and 30, Applicant requests that the nonstatutory obviousness-type double patenting rejections be held in abeyance until such time that the presence of otherwise-allowable subject matter is acknowledged. At such time, Applicant will file an appropriate terminal disclaimer, such as the terminal disclaimer attached at Exhibit A.

**CONCLUSION**

In view of the foregoing, Applicant believes that all rejections have been overcome and claims 23-26, 30 and 65-75 are in condition for allowance. The Examiner is invited to telephone the undersigned attorney to discuss any remaining issues. Early and favorable actions are respectfully solicited.

Respectfully submitted,



Fangli Chen, Ph.D.

Attorney for Applicant

Kirkpatrick & Lockhart Nicholson Graham LLP

One Lincoln Street

Boston, Massachusetts 02111-2950

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Reg. No. 51,551

Tel. No.: (617) 261-3198  
Fax No.: (617) 261-3175  
Customer Number: 022832